REMARKS

This application contains Claims 1-99, the status of which is as follows:

Claims 1, 5, 49, 53, and 61 are currently amended.

Claims 2-4, 6-15, 50-52, and 54-63 are as originally filed.

Claims 16-48 and 64-99 have been withdrawn.

No new matter has been added. Reconsideration is respectfully requested.

Claims 1 and 49 have been currently amended to remove the limitation that the overall duration of the extended pacing signal is greater than three times the chronaxie. In place of this limitation, the Claims now recite that the overall duration of the extended pacing signal is greater than 8 ms. This amendment is supported in the specification, for example, in the sixth paragraph of the Summary section of the application (page 7, lines 22-32), as follows:

> In preferred embodiments of the present invention, an improved cardiac pacemaker applies an extended pacing signal to the heart, ... Preferably, the overall duration is at least three times the chronaxie time. Further preferably, the overall duration is greater than 8 ms, more preferably, greater than 10 ms, and most preferably, greater than 20 ms. (Emphasis added.)

Claim Rejections - 35 USC 112

Claim 1 was rejected under 35 USC 112 "...since the Claim does not state whether the chronaxie time is predetermined or not. If not then the Claim is incomplete for omitting an element to determine a chronaxie time." The applicant submits that the currently-presented amendment to Claim 1 adequately addresses this rejection, as it replaces the words "three times a chronaxie time" with "8 ms."

At the end of the paragraph describing the rejection of Claim 1 under 35 USC 112, the Examiner noted that "the cited limitation 'electrical signals' is inferentially included and not positively recited in the Claims." The applicant respectfully submits with respect to this issue that amended Claim 1 and the remaining Claims clearly express the invention, and are not indefinite. Claim 1 as amended, for example, currently Claims "Apparatus ..., comprising one or more electrodes, which are adapted to convey electrical signals..." As in many presumptively-valid US patents, subsequent dependent Claims limit the scope of the Claimed invention by specifying aspects of the signal applied by the apparatus.

With respect to Claiming a connection to a human body, the applicant has amended Claims 1 and 5 as suggested by the Examiner, in order to overcome the rejection under 35 USC 112. A similar amendment has been made to Claim 53.

Claims 4 and 52 were rejected under 35 USC 112 "...for citing the limitation 'less than approximately 100 ms' since this would include pulse durations 0 ms, 1 ms and 2 ms not disclosed in the specification. Clarification is requested in the next communication." The applicant submits that the currently-presented amendments to independent Claims 1 and 49 (from which Claims 4 and 52 respectively depend) adequately address this rejection. In particular, it is noted that the independent Claims are now limited to an overall duration of the extended pacing signal being greater than 8 ms.

The Examiner noted that Claim 49 was "vague and indefinite for citing the limitation 'at three times'..." The applicant submits that the words "greater than 8 ms" in the currently-presented amendment to Claim 49 adequately address this issue.

Claim 61 has been currently amended to recite "A method according to Claim 60...," rather than "Apparatus according to Claim 60..."

Claim Rejections - 35 USC 102

Claims 1-4, 6, 7, 10, 11, 14, 15, 49-52, 54, 55, 58, 59, 62, and 63 were rejected under 35 USC 102(e) over Mouchawar (US Patent 5,906,633). The Examiner stated: "Mouchawar discloses the Claimed invention throughout the specification and particularly in column 6, 43-61." The identified text reads as follows:

> Further, as illustrated in FIG. 4, it is understood that if a ratio is calculated for the cardiac/sensory thresholds shown in FIG. 3, that this ratio has two asymptotic values. In particular, for a cardiac chronaxie of 3 milliseconds and sensory chronaxie of 0.5 milliseconds, the ratio between the cardiac/sensory threshold approaches a value of 6 at very short duration pulses. Therefore, for waveforms of very short duration, the sensory cells are six times more likely to be stimulated than the cardiac cells. Conversely, as illustrated in FIG. 4, as the duration of the therapeutic shock increases, e.g., is greater than 10 milliseconds, the ratio approaches an asymptotic value of 1. Therefore, therapeutic shocks that are greater than 10 milliseconds in duration, are equally likely to stimulate cardiac cells as they are to stimulate nerve cells. Therefore, applying a therapeutic shock that has a longer

> duration, e.g., 10 milliseconds or greater, will result in proportionally less sensory nerve stimulation while still stimulating cardiac cells as compared to shorter pulses.

The applicant respectfully submits that when Mouchawar describes "...the therapeutic shock that has a longer duration, e.g., 10 milliseconds or greater,..." he is referring to a cardioverting therapeutic shock or to a defibrillating therapeutic shock, and not to "an extended pacing signal" as Claimed in Claims 1 and 49 of the present patent application. The first paragraph of the Summary section of the Mouchawar patent, for example, states (column 2, line 62, to column 3, line 6):

> The aforementioned needs are satisfied by the implantable electrical device of the present invention which includes a controller that receives signals indicative of the heart function and provides output control signals to an output circuit that provides therapeutic shocks to the heart. Preferably, the output circuit can be configured to provide a first shock suitable for defibrillation purposes or a second shock suitable for purposes such as cardioversion in response to signals from the controller. In particular, the waveform of the second shock is configured to result in significantly less pain experienced by the patient than the pain that is felt by the patient when the first shock is provided. (Emphasis added.)

As Mouchawar frequently notes, cardioversion is associated with significant pain to the patient (for example, see column 1, line 66). In the text cited by the Examiner (column 6, lines 43-61) and elsewhere, Mouchawar teaches extending the duration of the applied cardioverting shock in order to allow a reduction of the applied cardioverting

signal amplitude and a consequent reduction of pain. The Mouchawar patent does not teach an apparatus or method for applying an extended pacing signal having an overall duration greater than 8 ms, and, the applicant respectfully submits, it would not have been obvious for a person of ordinary skill in the art, having read the Mouchawar patent, to conclude that pacing the heart using an extended pacing signal would be desirable.

In light of the above, the applicant respectfully submits that independent Claims 1 and 49 of the present patent application are allowable over Mouchawar. Claims 2-4, 6, 7, 10, 11, 14, 15, 50-52, 54, 55, 58, 59, 62, and 63, which are dependent on one or the other of the independent Claims and are therefore of narrower scope than the respective independent Claims, are also believed to be allowable over Mouchawar.

Claim Rejections - 35 USC 103

Claims 1, 5, 8-10, 49, 53, and 56-58 were rejected under 35 USC 103(a) as being unpatentable over Mann (US 6,311,089). Claims 1 and 49 as currently amended recite the limitation of "greater than 8 ms," and are believed by the applicant to address the 35 USC 103 rejection over Mann as well as the 35 USC 112 rejections discussed hereinabove. Nevertheless, Claims 1 and 49, even without the currently-presented amendments, are believed by the applicant to be non-obvious over Mann.

In a portion of the Mann patent including that cited by the Examiner (column 17, line 36, to column 18, line 33), it is stated:

> ... the pulse duration threshold at twice the rheobase is called the chronaxie point. The chronaxie point generally ranges between approximately 0.3 ms and 0.5 ms. ... The programmer 120 can provide graphs of the strength-duration curve with a 2:1 and 3:1 safety margin curve being

simultaneously displayed. The capture safety margin is a ratio defined by the programmed output divided by the measured threshold level. ...

In a pacemaker dependent patient, the usual recommendation ... is to set the pacemaker to provide a 2:1 safety margin with respect to the voltage threshold. This is a voltage that is 100% above the measured threshold voltage, although certain studies ... have recommended a 150% to 200% safety margin ...

...If the goal is to maximize patient safety, the output of the pacemaker should be programmed to its highest allowed level. This, however, will increase the power drain and accelerate the rate of power source depletion. If the capture threshold is stable at a very low level, a high output is wasteful and will unnecessarily shorten the pulse generator longevity.

The concept of safety margin attempts ... to protect the patient while maximizing the longevity of the implanted pulse generator by reducing the output and therefore reducing the power source drain. Hence, in the pacemaker dependent patient, a 2:1 or higher safety margin has been recommended.

...

Thus, Mann teaches that there is an essential tension between: (a) extending the duration of the applied pacing pulses, so as to improve safety, and (b) limiting the duration of the applied pacing pulses, so as to extend battery life. He notes that a 2:1

safety margin is the "usual recommendation," and that certain studies have recommended a safety margin ranging from 2.5:1 to 3:1 (i.e., 150% to 200%).

Mann states that the chronaxie "generally ranges between approximately 0.3 ms and 0.5 ms." Therefore, the highest safety margin listed by Mann (3:1), based on the stated upper end of the chronaxie range would produce a duration of 1.5 ms (i.e., 3 * 0.5 ms). Mann, as well as the study he cites, and "the usual recommendation for a conventional pacemaker" (column 17, lines 59-60), all teach pacing a heart in real human patients with a safety margin of up to 3:1. The cited prior art does not teach pacing with a safety margin higher than 3:1 (i.e., pacing with a duration greater than 1.5 ms, by the above-described calculation).

Amended Claims 1 and 49 of the present patent application recite an extended pacing signal having an overall duration of greater than 8 ms. In the language of Mann, this corresponds to a safety margin of between 16:1 and 26:1 (based on Mann's 0.3 ms - 0.5 ms chronaxie range). The applicant submits that (a) an extended pacing signal having an overall duration of greater than 8 ms is not taught by Mann, and (b) it would not have been obvious for a person of ordinary skill in the art, who has read Mann, to apply such a signal.

In addition, the applicant notes that increasing the duration of the pacing signal to greater than 8 ms (as Claimed in amended Claims 1 and 49) has been found by the applicant to have the benefit of improving various cardiac parameters, and does not simply result in a yet further increase in the safety margin. (See, for example, the experimental results obtained by the applicant and described in the present patent application.)

In light of this discussion, the applicant respectfully submits that currently-amended independent Claims 1 and 49 are not obvious in light of Mann. Claims 5, 8-10,

53, and 56-58, which are dependent on one or the other of the independent Claims and are therefore of narrower scope than the respective independent Claims, are also believed to be allowable over Mann.

Claims 12, 13, 60, and 61 were rejected under 35 USC 103(a), as being unpatentable over Mouchawar. The applicant respectfully submits that Claims 12, 13, 60, and 61 are in condition for allowance, based on the discussion above regarding Mouchawar and the resultant believed allowability over Mouchawar of independent Claims 1 and 49, which are broader in scope than these rejected Claims.

In view of the above remarks, the applicants respectfully submit that all of the Claims now pending in the present application are in condition for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,

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